Ivan T. Hofmann, CPA/CFF, CLP

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      UNITED STATES PATENT AND TRADEMARK OFFICE
       BEFORE THE PATENT TRIAL AND APPEAL BOARD
 2
 3
    MYLAN PHARMACEUTICALS INC.,
5
               Petitioner
6
                    v.
7
    JANSSEN ONCOLOGY, INC.
8
                Patent Owner
9
10
             Case IPR2016-01332
11
          Patent No. 8,822,438
12
13
             VIDEOTAPED DEPOSITION OF EXPERT
14
              IVAN T. HOFMANN, CPA/CFF, CLP
15
16
                    February 7, 2017
17
                         9:02 a.m.
18
                   700 13th Street NW
19
20
                   Washington, DC 20005
21
22
    Denise D. Vickery, CRR/RMR
23
                GOLKOW TECHNOLOGIES, INC.
            877.370.3377 ph | 917.591.5672 fax
24
                     deps@golkow.com
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Ivan T. Hofmann, CPA/CFF, CLP

	I Vali I . HOI main	/	CPA/CFF, CLIP
	Page 2		Page 4
1	APPEARANCES	1	PROCEEDINGS
2		2	
3	Attorneys for Petitioner:	3	THE VIDEOGRAPHER: We are on the
4	PERKINS COIE	4	record. The time now is 9:02.
5	700 13th Street NW	5	This marks the beginning of disk
6	Suite 600	6	No. 1 for the videotaped deposition
7	Washington, DC 20005	7	testimony of Ivan Hofmann in the matter
8	202.654.6200	8	of Mylan Pharmaceuticals Inc. versus
9		9	Janssen Oncology, Inc. This case is
10	BY: BRANDON M. WHITE, ESQ.	10	pending in United States Patent and
11	MARIA A. STUBBINGS, ESQ.	11	
	BMWhite@perkinscoie.com		Trademark Office before the Patent Trial
12	MStubbings@perkinscoie.com	12	and Appeal Board, case No. IPR
13		13	2016-01332.
14	Attorneys for Patent Owner:	14	Today's date is February 7, 2017.
15	SIDLEY AUSTIN LLP	15	This deposition is being conducted at 700
16	1501 K Street NW	16	13th Street, Northwest, Washington, DC.
17	Washington, DC 20005	17	Will all attorneys present please
18	202.736.8060	18	identify themselves and who they
19	BY: PAUL J. ZEGGER, ESQ.	19	represent.
20	pzegger@sidley.com	20	MR. ZEGGER: My name is Paul
21	1 66 7	21	Zegger. I'm with the firm of Sidley
22		22	Austin for the Patent Owner, Janssen
23	Also Present:	23	Oncology, Inc.
24	Michael Gay, Videographer	24	MR. WHITE: I'm Brandon White
		-	D 5
	Page 3	,	Page 5
1	INDEX	1	from Perkins Coie on behalf of the
2	EXAMINATION OF	2	Petitioner.
3	IVAN T. HOFMANN, CPA/CFF, CLP PAGE	3	MS. STUBBINGS: Maria Stubbings
4	BY MR. ZEGGER 5	4	from Perkins Coie also on behalf of
5		5	Petitioner.
6	EXHIBITS	6	THE VIDEOGRAPHER: My name is
7	HOFMANN DEPOSITION EXHIBITS PAGE	7	Michael Gay. I'm with Golkow
8	JANSSEN 2006 January 26, 2016 86	8	Technologies. Our court reporter today
9	Johnson & Johnson Reports	9	is Denise Vickery also with Golkow
10	2015 Fourth-Quarter Results	10	Technologies and will now swear in our
11	JANSSEN 2007 January 24, 2017 88	11	witness.
12	Johnson & Johnson Reports	12	
13	2016 Fourth-Quarter Results	13	IVAN T. HOFMANN, CPA/CFF, CLP
14	JANSSEN 2008 Concordia Pharmaceuticals v. 103	14	called for examination, and, after having been
15	Method Pharmaceuticals	15	duly sworn, was examined and testified as
16	PREVIOUSLY MARKED EXHIBITS REFERENCED	16	follows:
17	MYLAN 1017 Declaration of 5	17	THE VIDEOGRAPHER: You may
18	Ivan T. Hofmann, CPA/CFF, CLP	18	•
19	MYLAN 1012 June 4, 2013 Response to 63		proceed.
		19	EXAMINATION DV MD /TEGGED
20	Office Action of March 4, 2013	20	BY MR. ZEGGER:
21	MYLAN 1055 Top 50 pharmaceutical 105	21	Q. Good morning.
22	products by global sales 2014	22	A. Good morning.
23		23	Q. Let me show you Mylan Exhibit



Page 6 1 Sir, do you recognize this as 2 your declaration in the present IPR? 3 A. (Witness reviewing document). 4 I do. 5 Q. Is that your signature on page 6 24? 7 A. It is. 8 Q. Okay. You signed your 9 declaration back on June 30th of 2016? 10 A. Yes, sir. 11 Q. Is it correct that your 12 declaration deals with the issue of commercial 13 success as it relates to the issue of 14 Obviousness or nonobviousness of the '438 15 patent? 16 A. It does. 1 is sometimes considered. 2 Q. How much time did you spe the date of your declaration, June 30, 2 4 A. I don't have a firm number in mind. 6 Q. Well, from the time that your declaration declaration declaration, do you have some idea of the declaration declarat	016? were he hours
your declaration in the present IPR? A. (Witness reviewing document). I do. Q. Is that your signature on page A. It is. Q. Okay. You signed your declaration back on June 30th of 2016? A. Yes, sir. Q. Is it correct that your declaration deals with the issue of commercial success as it relates to the issue of patent? Q. Well, from the time that you declaration, do you have some idea of the incomplete of the inco	016? were he hours
3 A. (Witness reviewing document). 4 I do. 5 Q. Is that your signature on page 6 24? 7 A. It is. 8 Q. Okay. You signed your 9 declaration back on June 30th of 2016? 10 A. Yes, sir. 11 Q. Is it correct that your 12 declaration deals with the issue of commercial 13 success as it relates to the issue of 14 obviousness or nonobviousness of the '438 15 patent? 3 the date of your declaration, June 30, 2 4 A. I don't have a firm number in 5 mind. 6 Q. Well, from the time that your 7 first retained until the date of your declaration, June 30, 2 4 A. I don't have a firm number in 5 mind. 6 Q. Well, from the time that your 7 that you've spent? 10 A. I would say dozens. Beyond 11 I can't refine it. 12 Q. All right. Did anyone help y 13 A. Yes. 14 Q. Who? 15 A. In particular within my firm.	016? were he hours
I do. Q. Is that your signature on page Q. Well, from the time that your A. It is. Q. Okay. You signed your declaration back on June 30th of 2016? A. Yes, sir. Q. Is it correct that your declaration deals with the issue of commercial success as it relates to the issue of obviousness or nonobviousness of the '438 A. I don't have a firm number in mind. Q. Well, from the time that your first retained until the date of your declaration, do you have some idea of the '438 in the issue of commercial 10 A. I would say dozens. Beyond 11 I can't refine it. 12 Q. All right. Did anyone help your 13 A. Yes. 14 Q. Who? 15 A. In particular within my firm.	were the hours
Q. Is that your signature on page Q. Well, from the time that your A. It is. Q. Well, from the time that your first retained until the date of your declaration back on June 30th of 2016? A. Yes, sir. Q. Is it correct that your Q. Is it correct that your declaration deals with the issue of commercial success as it relates to the issue of obviousness or nonobviousness of the '438 beginning. The mind. Q. Well, from the time that your declaration, do you have some idea of the source of that you've spent? A. I would say dozens. Beyond Leading the mind. A. I would say dozens. Beyond A. I can't refine it. Q. All right. Did anyone help your A. Yes. A. Yes. A. In particular within my firm.	were he hours
6 24? 6 Q. Well, from the time that your 7 A. It is. 8 Q. Okay. You signed your 9 declaration back on June 30th of 2016? 10 A. Yes, sir. 11 Q. Is it correct that your 12 declaration deals with the issue of commercial 13 success as it relates to the issue of 14 obviousness or nonobviousness of the '438 15 patent? 6 Q. Well, from the time that your 7 first retained until the date of your 8 declaration, do you have some idea of the '438 of that you've spent? 10 A. I would say dozens. Beyond 11 I can't refine it. 12 Q. All right. Did anyone help your 13 A. Yes. 14 Q. Who? 15 A. In particular within my firm,	he hours
7 A. It is. 8 Q. Okay. You signed your 9 declaration back on June 30th of 2016? 10 A. Yes, sir. 11 Q. Is it correct that your 12 declaration deals with the issue of commercial 3 success as it relates to the issue of 14 obviousness or nonobviousness of the '438 15 patent? 7 first retained until the date of your 8 declaration, do you have some idea of the declaration, do you have some idea of the declaration, do you have some idea of the declaration do you have some idea of the declaration, do you have some idea of the declaration do you have some idea of the you've spent? 10 A. I would say dozens. Beyond 12 Q. All right. Did anyone help you've spent? 12 Q. All right. Did anyone help you've spent? 13 A. Yes. 14 Q. Who? 15 A. In particular within my firm.	he hours
Q. Okay. You signed your declaration back on June 30th of 2016? A. Yes, sir. Q. Is it correct that your declaration deals with the issue of commercial success as it relates to the issue of the '438 declaration, do you have some idea of the '438 A. I would say dozens. Beyond It can't refine it. Q. All right. Did anyone help your A. Yes. A. Yes. A. Yes. A. Yes. A. In particular within my firm,	
9 declaration back on June 30th of 2016? 10 A. Yes, sir. 11 Q. Is it correct that your 12 declaration deals with the issue of commercial 13 success as it relates to the issue of 14 obviousness or nonobviousness of the '438 15 patent? 9 that you've spent? 10 A. I would say dozens. Beyond 11 I can't refine it. 12 Q. All right. Did anyone help y 13 A. Yes. 14 Q. Who? 15 A. In particular within my firm,	
A. Yes, sir. Q. Is it correct that your declaration deals with the issue of commercial success as it relates to the issue of the '438 obviousness or nonobviousness of the '438 patent? A. I would say dozens. Beyond It I can't refine it. Q. All right. Did anyone help your A. Yes. A. Yes. A. Yes. A. I would say dozens. Beyond It I can't refine it. A. Yes. A. Yes. A. I would say dozens. Beyond It I can't refine it. A. I would say dozens. Beyond It I can't refine it. A. I would say dozens. Beyond It I can't refine it. A. I would say dozens. Beyond It I can't refine it. A. Yes. A. Yes. A. I would say dozens. Beyond It I can't refine it. A. Yes. A. I would say dozens. Beyond It I can't refine it. A. Yes. A. I would say dozens. Beyond It I can't refine it. A. Yes. A. I would say dozens. Beyond It I can't refine it. A. I would say dozens. Beyond It I can't refine it. A. I would say dozens. Beyond It I can't refine it. A. I would say dozens. Beyond It I can't refine it. A. I would say dozens. Beyond It I can	that,
Q. Is it correct that your 12 declaration deals with the issue of commercial 13 success as it relates to the issue of 14 obviousness or nonobviousness of the '438 15 patent? 11 I can't refine it. 12 Q. All right. Did anyone help y 13 A. Yes. 14 Q. Who? 15 A. In particular within my firm,	that,
declaration deals with the issue of commercial success as it relates to the issue of the '438 obviousness or nonobviousness of the '438 patent? Q. All right. Did anyone help y A. Yes. Q. Who? A. In particular within my firm,	
13 success as it relates to the issue of 14 obviousness or nonobviousness of the '438 15 patent? 13 A. Yes. 14 Q. Who? 15 A. In particular within my firm,	
13 success as it relates to the issue of 14 obviousness or nonobviousness of the '438 15 patent? 1 A. Yes. 14 Q. Who? 15 A. In particular within my firm,	ou?
patent?	
patent?	
Q. Okay. Do you have an advanced Q. What did they do?	
degree in economics? A. So for projects such as this, I	[
A. I have a bachelor's degree in 19 identify a team to assist me. We basica	
20 economics. 20 collaboratively review documents, evic	•
Q. Okay. Are you an oncologist? 21 information, and develop what become	
A. I am not.	-
Q. Okay. Do you have any education 23 supervision and direction, but they assi	•
or background in the field of oncology? 24 in, you know, pulling together what ult	
Page 7	Page 9
1 A. In terms of formal education, no. 1 becomes the issued declaration. 2 I've studied issues involving pharmaceutical 2 O Did anyone else help you?	
Q. Did diffolio olso help you.	
3 economics in many fields, including oncological 3 A. No.	
4 products. 4 Q. What criteria did you use to	
5 Q. Okay. Are you a urologist? 5 determine commercial success?	
6 A. No, sir. 6 A. Well, I think I explain my	
7 Q. Do you have any education or 7 opinions within my declaration.	
8 background in the field of urology? 8 The criteria as I understand it	
9 A. There again, no formal education, 9 or to look at the evidence that exists with	
but I've studied a variety of pharmaceutical 10 respect to the commercial performance of	
products that are directed to the field of product and whether there's a nexus between	
12 urology. 12 commercial performance and the asserte	d claims
Q. Okay. You're a certified public 13 of the patent at issue.	
14 accountant; correct? Q. Do you have a particular metr	ic
A. I am. ¹⁵ for the first part, the dollars part of the	
Q. Okay. When were you first 16 commercial success analysis?	
retained in connection with this IPR? MR. WHITE: Objection to for	
A. Sometime last May or June. 18 THE WITNESS: I think there	
Q. What were you asked to do? 19 number of different metrics that are	
20 A. I was asked to consider the 20 often looked at in a commercial suc	cess
21 economic issues surrounding claims of commercial 21 inquiry directed to the question of	
22 success and nexus with respect to the '438 22 obviousness.	
patent in particular and obviousness inquiry 23 BY MR. ZEGGER:	

Page 10 Page 12 performance with the claims of the patent dollar metric that you use with respect to 2 commercial success? at issue. 3 3 MR. WHITE: Objection to form. BY MR. ZEGGER: 4 THE WITNESS: I don't believe Q. Well, let me put it this way. 5 If there were a nexus and there there are particular bright-line metrics 6 with respect to commercial success. It's weren't a blocking patent, would you have found 7 a very facts and circumstances intensive that there was commercial success in this case? 8 inquiry. MR. WHITE: Objection to form. 9 9 BY MR. ZEGGER: THE WITNESS: Well, I think 10 10 Q. Do you think Zytiga was a that's a counterfactual hypothetical as I 11 11 commercial success? understand to the landscape. So I think 12 12 My opinions are explained within there's a hazard in entertaining Α. 13 13 counterfactual hypotheticals. my declaration. 14 14 I think that very clearly there My opinion is that commercial 15 performance does not provide objective indicia 15 is a blocking patent, very clearly there of nonobviousness in the form of commercial 16 is a lack of nexus. I don't -- I don't 17 17 success for the reasons outlined in my quarrel with the fact that there are 18 declaration. 18 relatively significant sales of Zytiga, 19 19 O. Okay. One of those reasons was but in context that I provide. 20 20 lack of nexus; is that right? So, you know, I think that the 21 21 opinions and conclusions with respect to Α. Among others. 22 22 O. Okay. Another reason was a the lack of objective indicia are pretty blocking patent; is that right? 23 clearly laid out in my declaration. 24 24 BY MR. ZEGGER: A. Yes. Page 11 Page 13 Now, in Attachment A-1 of your 1 Okay. But other than those, were 1 declaration, you have a list of materials that there any other reasons for your opinion that 3 you considered; is that right? there was no commercial success? 4 4 That's right, at least as of the I think those are -- those are date of my declaration. central opinions, and I think the rest of my 6 opinions are laid out in my declaration. Are all -- is that a complete 7 Okay. But your opinion is not list of the materials that were provided to you based on any lack of dollar sales of Zytiga; is in connection with this IPR as of the date of 9 your declaration? that right? 10 10 Α. Well --Yeah. As of the date of my 11 declaration, it's my attempt to administratively MR. WHITE: Objection. Form. 12 gather the information. To the extent I cite THE WITNESS: -- I think my 13 opinions are expressed in my report. I other things within the body of my declaration, 14 provide, I think, context that's lacking those would also be included. 15 15 in the record as it exists with respect O. Were all of those materials 16 16 provided to you? to the findings of the examiner. 17 17 So I do, I think, provide context It would be some combination of 18 to some of the claims with respect to the materials provided as well as, you know, things 19 I and my team pulled directly from the IPR commercial performance of Zytiga, but 20 ultimately my -- my opinions regarding docket and/or independent research. 21 the lack of objective indicia of 21 On your list of materials



22

considered, can you identify those that you and

your team found on your own as opposed to being

nonobviousness tend to surround the

existence of the blocking patent and a

	Ivan T. Holmani	n,	CPA/CFF, CLP
	Page 14		Page 16
1	A. I can't as I sit here right now.	1	Q. Well, would you be surprised if
2	Q. Could you look at your	2	portions of your declaration are identical to
3	declaration, page 3, Footnote 1.	3	those in Dr. McDuff's declaration?
4	Are you there?	4	A. Not at all.
5	A. I am.	5	Q. Okay. How many times have you
6	Q. Okay. Now, that mentions a	6	performed financial and economic analyses
7	declaration of DeForest McDuff in an IPR brought	7	relating to prescription pharmaceutical
8	by Amerigen; is that right?	8	products?
9	A. It does.	9	A. I mean, I've studied virtually
10	Q. And your footnote states:	10	every therapeutic class of drugs, clearly more
11	"I have reviewed the McDuff	11	than a hundred projects both in and outside of a
12	declaration in forming my opinions."	12	dispute setting. I've studied pharmaceutical
13	Is that right?	13	products and economic issues surrounding them
14	A. Among other things.	14	Q. Did any relate to cancer drugs?
15	Q. Okay. Well, did you, in fact,	15	A. Yes.
16	review the McDuff December 4, 2015 declaration	16	Q. How many?
17	in IPR 2016-00286?	17	A. I haven't cataloged it
18	A. I did.	18	specifically that way, but I would say dozens.
19	Q. Is it your understanding that	19	Q. Well, did any of the cases you've
20	Dr. McDuff is an economist who was hired by	20	worked on in the past relate to drugs to treat
21	Amerigen in a different IPR?	21	prostate cancer?
22	A. I think Amerigen as well as	22	A. Again, I haven't cataloged it
23	another petitioner.	23	that way. I'm sure they have.
24	Q. Okay. Did you rely upon	24	Q. Can you recall any matters that
	Page 15		Page 17
1	Dr. McDuff's declaration in forming opinions set	1	you've worked on relating to drugs to treat
2	forth in your declaration?	2	prostate cancer?
3	MR. WHITE: Objection to form.	3	MR. WHITE: And I just caution
4	THE WITNESS: I wouldn't say I	4	the witness to the extent anything is
5	relied upon it. I would say I reviewed	5	confidential about your prior engagements
6	it, and it was part of the information	6	with clients, this transcript is public.
7	that I considered with respect to forming	7	So that's my caution.
8	my opinions.	8	THE WITNESS: Yeah. Like I said,
9	BY MR. ZEGGER:	9	I haven't really cataloged it in the way
10	Q. Did you talk to Dr. McDuff about	10	you're asking it, and I am concerned
11	his declaration?	11	because a lot of the work that I do is
12	A. No, sir.	12	outside of a dispute setting and are
13	Q. Did you copy portions of	13	confidential terms.
14	Dr. McDuff's declaration for use in your	14	So as I sit here right now, I'm
15	declaration?	15	not sure that I can get into projects or
16	A. I certainly reviewed Dr. McDuff's	16	that able to provide specifics.
17	declaration, and there are certain areas of my	17	BY MR. ZEGGER:
18	declaration where I followed the language that	18	Q. Well, I'm not asking you to
19	already existed as as one can see reviewing	19	divulge anything that would be of a confidential
20	my declaration compared to his.	20	nature.
21	Q. Well, have you compared your	21	I'm just asking whether any of
22	declaration to that of Dr. McDuff's to see if	22	your prior work has related to drugs to treat
		1	The result of th



any portions are the same?

²³ prostate cancer.

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